

III. Remarks

Reconsideration and allowance of the subject application are respectfully requested.

Claims 18-37 are pending in the application. Claims 18, 25, 31, and 37 are independent.

The undersigned and inventor Dr. Kieran Murphy would like to thank Examiner Thanh for the cordial and productive interview of October 5, 2005. The Examiner's helpful comments and suggestions were instrumental in preparing this response.

As discussed at the interview, Applicants have added new Claims 18-37 to afford themselves a scope of protection commensurate with the disclosure. The new claims are fully supported in the specification and drawings, and are believed to be allowable for the reasons to be developed below.

Claims 13-17 were rejected as being unpatentable over Howe and Goebel, for the reasons discussed at pages 2-4 of the Office Action. Applicants respectfully traverse all art rejections.

As described by Dr. Murphy at the interview, the present invention, as set forth in independent Claim 18, includes a novel combination of structure and/or function whereby a cerebral spinal fluid pressure measurement catheter includes a narrow end to be inserted through a puncture into

the subarachnoid space within the lumbar spinal dura of a patient. The continuously tapered outer surface of the catheter forms a lumbar spinal dura pressure seal at the puncture, between an exterior of the catheter and an interior of the lumbar spinal dura. Notably, the outer surface of the catheter tapers continuously from the narrow end to the seal, to cause the cerebral spinal fluid pressure to be retained inside the lumbar spinal dura. This way, the physician has tactile feedback from the continuously tapered catheter when the lumbar spinal dura is encountered and sealed, letting the physician know when to stop inserting the spinal catheter.

In contrast, each of Howe and Goebel fails to disclose a continuously tapering outer surface of a spinal catheter which forms a seal at the lumbar spinal dura puncture. Howe discloses a needle with an abrupt taper 7/32 inches from the distal end. Goebel discloses a catheter with an abrupt taper two inches from the distal end. Neither discloses any continuous tapered catheter outer surface forming a seal at the lumbar spinal dura puncture.

Independent Claim 25 recites a novel combination of structure and/or function whereby a cerebral spinal fluid catheter includes a distal end configured for insertion through a puncture in the lumbar spinal dura into the cerebral spinal fluid-containing subarachnoid space therewithin, where the distal is less than 14 gauge. The

catheter proximal end is wider than the distal end. An intermediate catheter portion is disposed between the distal end and the proximal end. The intermediate catheter portion is greater than 14 gauge, and the catheter is uniformly tapered from the distal end to the intermediate portion. The intermediate portion is configured to form a lumbar spinal dura seal at the puncture, between the exterior of the catheter and an interior of the lumbar spinal dura, to cause cerebral spinal fluid pressure to be substantially retained inside the lumbar spinal dura.

Again, each of Howe and Goebel fails to disclose a uniformly tapered outer surface of a spinal catheter which forms a seal at the lumbar spinal dura puncture to cause cerebral spinal fluid pressure to be substantially retained inside the lumbar spinal dura. Howe discloses a 25 gauge needle tip with an abrupt taper up to 20 gauge about 7/32 inches from the tip. Goebel discloses a catheter with a 22 gauge tip with an abrupt taper up to 20 gauge about two inches from the distal end. Neither discloses any uniform taper catheter outer surface forming a seal at the lumbar spinal dura puncture.

Independent Claim 34 recites a novel combination of structure and/or function whereby a cerebral spinal fluid kit includes (i) a hollow needle configured to form a puncture in

the lumbar spinal dura of a patient; (ii) a guidewire configured to be inserted through the interior of the needle, through the puncture in the lumbar spinal dura, and into the subarachnoid space therewithin, the guidewire and the needle being configured such that the needle can be withdrawn from the guidewire; and (iii) a cerebral spinal fluid catheter. The cerebral spinal fluid catheter includes: (i) a distal end configured for insertion through the puncture in the lumbar spinal dura into the cerebral spinal fluid-containing subarachnoid space therewithin; (ii) a proximal end wider than the distal end; and (iii) an intermediate portion disposed between the distal end and the proximal end, said intermediate portion being greater than said puncture. The spinal catheter being uniformly tapered from the distal end to the intermediate portion. The intermediate portion is configured to form a lumbar spinal dura seal at the puncture between an exterior of said catheter and an interior of the lumbar spinal dura to cause cerebral spinal fluid pressure to be substantially retained inside the lumbar spinal dura.

Again, each of Howe and Goebel fails to disclose a uniformly tapered outer surface of a spinal catheter which forms a seal at the lumbar spinal dura puncture to cause cerebral spinal fluid pressure to be substantially retained inside the lumbar spinal dura.

Independent Claim 37 recites a novel combination of steps whereby a method of installing a cerebral fluid catheter into the lumbar spinal dura of a patient, includes the steps of: (i) puncturing the lumbar spinal dura of a patient with a hollow needle to form a puncture; (ii) inserting a guidewire through the interior of the needle, through the puncture in the lumbar spinal dura, and into the subarachnoid space therewithin (iii) withdrawing the needle from the guidewire; and (iv) installing a cerebral spinal fluid catheter over the guidewire into the subarachnoid space within the the lumbar spinal dura, said catheter having a distal end and a proximal end. The installing step including the substeps of: (iva) installing the distal end of the catheter through the puncture in the lumbar spinal dura into the cerebral spinal fluid-containing subarachnoid space therewithin, said distal end being narrower than the puncture; (ivb) continuing to install the distal end of the catheter through the puncture until an intermediate portion of the catheter disposed between said distal end and said proximal end forms a lumbar spinal dura seal with said puncture, said catheter being uniformly tapered from said distal end to said intermediate portion, said intermediate portion forming a lumbar spinal dura seal at the puncture between an exterior of said catheter and an interior of the lumbar spinal dura to cause cerebral spinal fluid pressure to be substantially retained inside the lumbar spinal dura.

Neither Howe nor Goebel discloses or suggests such method steps.

In view of the above, it is believed that this application is now in condition for allowance, and a Notice thereof is respectfully requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3507. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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